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EXAMINER
SAIDHA, TEKCHAND

ART UNIT	PAPER NUMBER
1652	7

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/812502	Anderson et al.
Examiner	**Group Art Unit**
Saidha, T.	1652

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on Preliminary of 3/20/01.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 20-23 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 20-23 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☒ received in Application No. (Series Code/Serial Number) 08/454295.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

DETAILED ACTION

1. The Preliminary Amendment dated 3.30.01 (Paper No. 5) has been entered. Claims 20-23 are pending and under consideration in this examination.

2. Acknowledgment is made of applicants' claim for priority based on an application filed in Australia on 12.16.1992.

3. ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The signatures and dates of second and third inventors are not legible. A legible copy is required.

4. ***Abstract***

*The abstract should be in narrative form and generally limited to a single paragraph within the range of 50 to 250 words. The form and legal phraseology often used in patent claims, such as "means" and "said", should be avoided in the abstract. The abstract should sufficiently describe the disclosure to assist readers in deciding whether there is a need for consulting the full patent text for details. MPEP 608.01(b).

The abstract has been modified accordingly and the word 'said' on lines 5, 6 & 7 is replaced with the word 'the', instead.

5. ***Sequence Rules***

The instant specification on pages 9 (line 33), page 10 (lines 7, 11 & 27) & page 11 (line 10), present amino acid sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), but fails to comply with the requirements. According to 37 CFR 1.821-825, every disclosed amino acid sequence of **four or more residues** or 10 or more nucleotides must be identified by a SEQ ID NO. The amino acid sequences presented do not have SEQ ID Nos. In order to comply with the sequence rules Applicants must identify these sequences by providing SEQ ID NO :, and where required provide a new version of the sequence listing and disk.

There is sequence present in claim 20, which lack description by the appropriate sequence identifier set forth in the "Sequence Listing" as required by 37 CFR § 1.821(d).

Specification

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

7. **35 U.S.C. § 101**

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 20-23 are rejected under 35 U.S.C. § 101 because the claimed invention is directed toward non-statutory subject matter.

In the absence of the hand of man, naturally occurring proteins and/or nucleic acids are considered non-statutory subject matter. *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims 20-23 to recite wording such as "An isolated or purified...".

8. ***Written Description***

Claims 20-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 20-23 are directed to any protease sensitive peptide or a nucleic acid encoding such a peptide 'the claimed genus', wherein X_1 & X_2 may be any of the amino acid residues but preferably 'Lys' residues; and wherein R_1 & R_2 may be any of the amino acid residues peptide, polypeptide, a protein, or an alkyl.., nitro...alkylaryloxy group and the like. Thus a generalized genus is claimed. The specification on page 10, lines 1-3 assumes that such a discovery of a protease sensitive peptide will enable the engineering of peptides and polypeptides capable of being processed in a plant by cleavage. No specific examples are presented, however. The prior art is silent about such or similar constructs that a skilled artisan could use in order to practice such an invention. The specification does not describe in clear terms even a single or representative number of species to the genus. A

'representative number of species' requires that the species which are expressly described be representative of the entire genus. Therefore, without a clear description of even a single functional protease sensitive peptide construct or the nucleic acid encoding the same, further modification that are expected to be made in substituting the R_1 & R_2 or X_1 & X_2 for other compounds would require adequate written description of the genus, which cannot be achieved by disclosing a generalized genus. In an unpredictable art, such as the instant one, wherein a peptide construct and the nucleic acid encoding such a construct - be made by amino acid or peptide or alkyl or nitro group substitution, adequate written description requirement of a genus cannot be achieved by disclosing a generic formula without clear-cut identifying characteristics, such as structure or functional activity of the peptide construct or nucleic acid encoding the same, written description for each member within the genus will be necessary and such is not described. Therefore, the written description requirement is not satisfied.

9. ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams [U.S.P. 5,032,396, July 16, 1991]. Williams teaches a peptide sequence (see Table 2) comprising the amino

acid sequence : .....GLN-**LYS-LYS-ASN-ASP**-ALA..... [where X_1 & X_2 are Lys residues and R_1 are amino acid(s) GLN or residues 1-102 ; & R_2 are amino acid(s) ALA or residues 107-129] which by virtue of the structure is functionally a protease sensitive peptide, because protease acts between residues Asn-Asp. The claims are written so broadly as to be anticipated by the reference.

10. ***Claim Rejections - 35 U.S.C. § 103***

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suggs et al. [Suggs et al.[PNAS, USA.,78(11) : 6613-6617] in view of Williams [U.S.P. 5,032,396, July 16, 1991].

Suggs et al. teach the use of mixtures of chemically synthesized oligodeoxyribonucleotides as hybridization probes for the isolation of specific cloned DNA sequences. The approach is to "chemically synthesize a mixture of oligonucleotides that represent all possible codon combinations for a small portion of the amino acid sequence of a given protein." Once a protein, in this case the protease of the generalized structure (R1-**X1- X2 -ASN-ASP**- R2) or the specific sequence [GLN-**LYS-LYS-ASN-ASP**-ALA] of Williams, is purified and known. Under the principle that one sequence must be complementary to the DNA for that protein, "the complementary oligonucleotide will form a perfectly base paired duplex with the DNA from the coding region...". Thus, mixed

oligonucleotide probes allow the isolation of DNA sequences for any protein with a known or obtainable portion of the amino acid sequence.

In light of the method of Suggs et al. for isolating the appropriate DNA sequence coding for a particular protein, it would have been obvious to one of ordinary skill in the art to use these methods to determine the coding nucleotide sequence of protease in murine (IL-7) disclose the fact that murine produces the protease and therefore possesses that gene. The state of the art at the time the invention was made dictates that, since the culturing and recovery of the naturally-occurring enzyme from its natural source yields small, and at times unstable, amounts, production of such proteins by recombinant means is the single best technique to dramatically increase yield and insure stable production of the protein. One would not have to probe a library of possible sources to find a similar gene, as Williams provides sufficient motivation to merely determine the sequence from the known source. Thus, the nucleic acid molecule of the claim 23 is not considered patentable.

From this, one utilizing the ordinary level of skill in the art could easily assemble various expression vectors containing either a recovered full length clone, or the appropriate fragments ligated at the corresponding restriction sites. The transformation of host cells with this vector is also within the ordinary skill in the art, as a variety of cell lines, both prokaryotic and eukaryotic, human (mammalian) included, are well documented and commonly used. The selection of the appropriate plasmids, promoters, and cell lines for proper expression of the inserted gene is merely a matter of judicious selection, within the scope of ability of one ordinarily skilled in the art.

11. ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(a) Claims 20-23 are rejected under the judicially created doctrine of double patenting over claims 1-5 of U. S. Patent No. 6,261,821 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The instant claims are drawn to a generalized protease sensitive peptide and the encoding nucleic acid compared to the patented claims in U. S. Patent No. 6,261,821, which are drawn to specific protease sensitive peptide and the encoding nucleic acid.

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is (703) 305-6595. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group in the Technology Center is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

T K Saidha

Tekchand Saidha
Primary Examiner, Art Unit 1652
May 3, 2002